Opening Statement of the Honorable Joe Pitts
Subcommittee on Health
Markup on "H.R. 1407 and a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the pharmaceutical distribution supply chain"
May 7, 2013

(As Prepared for Delivery)

Tomorrow, the subcommittee will consider legislation reauthorizing the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) and a discussion draft on securing the pharmaceutical distribution supply chain, also known as "track and trace."

On April 9, this subcommittee held a hearing on ADUFA and AGDUFA, two successful user fee programs at FDA that expire on September 30, 2013.

In 2003, ADUFA I was authorized to help the FDA review of animal drugs.

Similar to the Prescription Drug User Fee for human drugs, under ADUFA, FDA collected funds to help expedite the new animal drug approval process, reduce the application backlog and improve communications with drug sponsors.

The program was authorized for five years and Congress renewed the program for an additional five years in ADUFA II in 2008.

FDA and industry have negotiated an agreement regarding the size and scope of ADUFA III, which would extend the program through FY2018 and these recommendations were delivered to the committee in February.

Under the negotiated proposal, industry would pay approximately $23.6 million in FY2014, and similar amounts, adjusted for inflation, for FYs 2015-2018.

AGDUFA I, ADUFA's generic cousin, was first authorized in 2008 for five years, in order to improve the review of abbreviated new animal drug applications (ANADAS), eliminate application backlogs, and reduce review times.

FDA and industry have also negotiated an agreement for AGDUFA II.

Under the proposed AGDUFA II agreement, industry would pay:

- $7,328,000 in FY2014 (which allows for the hiring of 22 FTEs and includes a one-time cost of$850,000 for information technology);
- $6,944,000 in FY2015;
- $7,429,000 in FY2016;
- $7,936,000 in FY2017; and
- $8,467,000 in FY2018.

The legislation to reauthorize ADUFA III, H.R. 1407, was introduced by Rep. John Shimkus, and the AGDUFA II reauthorization, H.R. 1408, was introduced by Rep. Cory Gardner. Tomorrow, we will consider an amendment in the nature of a substitute to combine both bills.

Regarding track and trace, on April 25, the Health Subcommittee held a hearing on the Latta-Matheson discussion draft, which provides a uniform framework for securing the downstream pharmaceutical supply chain, which includes manufacturers, wholesale distributors, pharmacies, repackagers, and third-party logistics providers.

Securing the supply chain through this bill will help ensure that counterfeit or stolen drugs do not enter the supply chain and harm patients. It will also ensure that overlapping red tape does not impose dramatic costs on patients in the form of higher prescription drug costs or potential drug shortages.

Several changes have been made to the discussion draft since the hearing. Most notably, the updated discussion draft contains two important changes to address concerns from some of my colleagues. First, it ensures that a prescription drug product's transaction history will be required starting on January 1, 2015. It also includes a framework to move towards unit level tracking in a manner that ensures a collaborative process between FDA and stakeholders, respects the unique nature of small businesses and dispensers, and most importantly, is practical and achievable.